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ANNEX II

K023236

510 (K) SUMMARY
SAFETY AND EFFECTIVENESS SUMMARY
(in accordance with SMDA 1990)

SENSICARE®-C SYNTHETIC POLYISOPRENE POWDER-FREE SURGICAL GLOVES
Classification Name: Surgeon's Glove, Type 2 (21 CFR 878.4460)

(Lavender Color)

The device in this 510(k) submission is the SensiCare®-C Synthetic Polyisoprene Powder-free Surgical Glove (Classification number 79KGO). The SensiCare®-C Synthetic Polyisoprene Powder-free Surgical Glove is a sterile, synthetic rubber latex surgical glove. These gloves are intended to be used as a barrier by providing protection for surgical personnel and patients against microbial migration and to protect a surgical wound from contamination.

The SensiCare®-C Synthetic Polyisoprene Powder-Free Surgical Gloves are substantially equivalent to the SensiCare™ Synthetic Polyisoprene Powder-Free Surgical Gloves previously submitted and cleared under 510(k) number K002933. The only difference is that this submission is for the inclusion of colorants in the glove substrate. The safety and effectiveness of the device is maintained. The results of the safety, efficacy, and performance testing of the SensiCare®-C Synthetic Polyisoprene Powder-Free Surgical Gloves are detailed in this 510(k) submission and are summarized as follows:

1. The gloves are substantially equivalent to the sterile SensiCare™ Synthetic Polyisoprene Powder-Free Surgical Gloves previously submitted and cleared under 510(k) number K002933.

2. The gloves meet all ASTM D3577-01a$^{\epsilon 2}$, requirements for sterility, freedom from holes, physical properties, and physical dimensions. The gloves meet the requirements of 21 CFR 800.20 for freedom from pinholes.

3. The gloves have been tested and have been shown to be non-irritating and non-sensitizing under test conditions when evaluated in accordance with internationally recognized test methods.

4. The gloves have been tested per ASTM D6124, and are labeled as powder-free.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2002

Mr. Roy E. Moser
Manager, Corporate Regulatory Affairs
Maxxim Medical, Incorporated
4750 118th Avenue North
Clearwater, Florida 33717

Re: K023236
Trade/Device Name: SensiCare-C Synthetic Polysoprene Powder-Free Surgical Gloves (Lavender Color)
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgical Gloves
Regulatory Class: I
Product Code: KGO
Dated: September 23, 2002
Received: September 27, 2002

Dear Mr. Moser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: Maxxim Medical Inc.

510(k) Number: K 023236

Device Name: SensiCare-C Synthetic Polysoprene Power-Free Surgical Gloves
(Lavender color)

Indications for use: A surgeon glove is a disposable device intended for medical purposes that is worn on the surgeon's hand to prevent contamination between patient and surgeon.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023236